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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/805,796	03/22/2004	James F. McGuckin JR.	1267	1069
7590	11/30/2006		EXAMINER	
NEIL D. GERSHON REX MEDICAL 1011 HIGH RIDGE RD Stamford, CT 06905			SONNETT, KATHLEEN C	
			ART UNIT	PAPER NUMBER
				3731

DATE MAILED: 11/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)
	10/805,796	MCGUCKIN ET AL.
	Examiner	Art Unit
	Kathleen Sonnett	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 29 September 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-15 and 18-26 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 22-25 is/are allowed.
- 6) Claim(s) 1-15, 18-20, and 26 is/are rejected.
- 7) Claim(s) 21 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	6) <input type="checkbox"/> Other: _____.

DETAILED ACTION

Terminal Disclaimer

1. The terminal disclaimer filed on 10/11/2006 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on patent application 10/805,796 has been reviewed and is accepted. The terminal disclaimer has been recorded. Therefore, the provisional double patenting rejections of claims 1-2, 4, 8, 12, 13-15, 18, and 21-23 have been withdrawn.

Response to Arguments

2. Applicant's arguments filed 9/29/2006 have been fully considered but they are not persuasive.

3. Regarding claim 12, applicant argues that the amendments to claim 12 distinguish the claim from the prior art of Palmaz (U.S. 4,793,348). Applicant argues that the Palmaz struts do not divide as they are shown to be the same width before and after the divide. However, the examiner respectfully disagrees. The "starting" strut can divide into oppositely directed struts with the same dimension as the "starting" strut. The amended claim now requires that the "starting" struts have a larger dimension than the oppositely directed struts. However, the claim does not indicate what dimension of the struts is being considered. Therefore, as described in more detail in the 35 U.S.C. 102 rejections below, dimensions other than the width of the strut have been considered.

4. Regarding claim 20, the hook of Bosma et al. (U.S. 6,989,021) is being considered a single hook with two ears in view of applicant's specification (see fig. 13b-13e; [0090] and [0091] of printed publication). The examiner disagrees with applicant's assertion that the hook portion of Bosma cannot be accessed from a side direction after reviewing fig. 4 of Bosma.

Art Unit: 3731

Furthermore, the hook has an inner surface exposed and it is dimensioned to receive a portion of a retrieval device as the entire hook is dimensioned to receive a portion of a retrieval device.

5. Regarding the objections to claims 21 and 22 presented in the office action dated 7/11/2006, the examiner appreciates the amendments made to claims 21 and 22 meant to clarify the scope of the claims. However, the examiner has suggested further changes to claim 21 as described below in the objection to claim 21.

Claim Objections

6. **Claim 21** is objected to because of the following informalities: the wording of claim 21 claims the hooks of the first set of hooks having a transverse dimension greater than a transverse dimension of the hooks of the second set of hooks. It is not clear that each hook of the first set of hooks has a transverse dimension greater than a transverse dimension of each of the hooks of the second set of hooks. Appropriate correction is required.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 12-15** are rejected under 35 U.S.C. 102(b) as being anticipated by Palmaz (U.S. 4,793,348). Palmaz discloses a vessel filter that is movable from a collapsed position to a substantially bell-shaped expanded position comprising a first and second region. The first region has a converging region at a first end portion (60) and the second region has a flared mounting portion (54) for mounting the filter within the vessel as seen in Fig. 2. The second

region includes a plurality of struts extending from the filter portion and dividing into oppositely directed struts at a first end and then converging with an oppositely directed strut of an adjacent strut. The struts have a first dimension and divide at a first end into oppositely directed struts of a second dimension smaller than the first dimension. Looking at fig 1A of the collapsed filter, spaces 42 are longer than spaces 44a. Considering one of the struts 30a, if you start at the distal end (28) and move until it splits at 32a into oppositely directed struts which further split at 32b, the first struts are longer than the second set of struts. Note: The language of the claim ("having a first dimension....") allows the use of any dimension including the length of the strut.

9. Regarding claims 13 and 15, see hooks (54).
10. Regarding claim 14, the oppositely directed struts emanating from the end of another strut are rejoined at a second end.
11. **Claim 20 is rejected under 35 U.S.C. 102(e)** as being anticipated by Bosma et al. (U.S. 6,989,021). Bosma et al. discloses a vessel filter comprising a first region and a second region, the first region including a filtering section for capturing particles and having a first transverse dimension, the second region including a mounting section for mounting the filter within the vessel, the mounting section having a second transverse dimension greater than the first transverse dimension and including vessel engaging structure (26) to retain the filter, the first region further including a retrieval region (18) that includes a single hook. Although called twin hooks by Bosma et al., element (22) is being considered a single hook with two ears. In applicant's specification, a similar hook (shown in fig. 13b-13e) is called a hook with two ears (see [0090] and [0091]). The hook has a cutout exposing an internal annular surface (Fig. 3 and 4, "22"). The hook is meant to ease retrieval by a retrieving device and is therefore dimensioned to receive a portion of a retrieval sheath, such as a hook. The hook also has an inner surface

exposed and dimensioned to receive a portion of a retrieval device since it is provided for the purpose of being snared with a retrieving device.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. **Claims 1-8 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz (U.S. 4,793,348) in view of Weldon et al. (U.S. 6,468,290).** Palmaz discloses a vessel filter comprising a first region and a second region, the filter movable between a collapsed position for delivery to the vessel and an expanded position for placement within the vessel, the first region having a filter portion having a converging region at a first end portion to direct particles toward the center of the filter, the second region being flared in the expanded position to have a transverse dimension increasing toward a second end portion opposite the first end portion and including a plurality of spaced apart struts (50) with adjacent struts being joined (Fig. 1B and 2). Palmaz discloses vessel engaging hooks (54) at the ends of the struts, but does not disclose that there are a first set of hooks and a second set of hooks, the first set of hooks being axially spaced from the second set of hooks so the second set of hooks terminates proximally of the first set of hooks.

14. However, Weldon et al. discloses that it is old and well known to employ two sets of hooks on a filtering device, a first set being axially spaced from a second set such that the second set of hooks terminates proximally. Weldon et al. discloses that this two point contact at different planes provides several advantages including the following: reduces the collapsing of

the cava by reinforcement of the walls, reduces contact pressure on the vein walls originating from each of the wire ends which in turn reduces trauma to the vessel wall and makes removal of the device easier, and reduces likelihood of filter tilting (see col. 4 ll. 40-64). Therefore, it would have been obvious to one of ordinary skill in the art to modify the device of Palmaz to include a first set of hooks and a second set of hooks, the first set of hooks being axially spaced from the second set of hooks so the second set of hooks terminates proximally of the first set of hooks as made obvious by Weldon et al. in order to gain the advantages listed above.

15. Regarding claims 2, 3, and 10, the adjacent struts are joined by two connecting struts (30a, 30b), each of the two connecting struts extending inwardly toward the other connecting struts. As seen in Fig. 2, the connecting struts converge at their ends to form a substantially V-shaped configuration.

16. Regarding claim 4, the vessel engaging hooks extend from a terminal end of the struts (54).

17. Regarding claims 5-7, the struts divide at an end portion (34) to form two connecting struts that extend away from each other, each connecting strut extending toward the connecting strut of an adjacent strut. The connecting struts of adjacent struts are joined at an intermediate region and further extend away from each other to join the connecting strut emanating from the same strut. As seen in Fig. 2, the connecting struts form a closed oval like region (44b).

18. Regarding claim 8, Palmaz discloses that filters made of a shape memory material such as nitinol are old and well known. Palmaz further discloses the filter is formed from a laser cut tube composed of shape memory material (col. 3 line 9 and col. 7 lines 53-57).

19. Regarding claim 11, the adjacent struts are interconnected by strut portions that initially extend away from each other and then extend towards one another forming a closed geometric configuration (44b).

20. **Claim 9** is rejected under 35 U.S.C. 103(a) as being unpatentable over Palmaz in view of Weldon et al. as applied to claim 1 above, and further in view of Russell (U.S. 6,958,074). Modified Palmaz discloses the invention substantially as stated above, but fails to disclose a plurality of axially spaced cutouts or recesses configured to receive a removal tool such as a retrieval snare to remove the filter fro the vessel.

21. However, Russell discloses that it is old and well known in the art to include a structure on the end of a vessel filter such as a hook or a coil as seen in Fig. 9D. This structure allows the filter be grasped or snared by a retrieval instrument for eventual removal of the filter (col. 9 lines 43-45). The helical structure has a plurality of recesses in the retrieval instrument can hook on to. Therefore, it would have been obvious to one of ordinary skill in the art to include a helical structure on the end of the device of Palmaz as made obvious by Russell in order to gain the advantage of having being able to easily remove the filter once it is no longer needed.

22. **Claims 18-20 and 26** are rejected under 35 U.S.C. 103(a) as being unpatentable over Weldon et al. in view of Bosma et al. (U.S. 6,989,021). Weldon et al. disclose a vessel filter comprising a first region at the first end portion and at the second end region, the first region including a filtering section for capturing particles and having a first transverse dimension at a first terminal end of the filter, the second region including a mounting section for mounting the filter within the vessel, the mounting section having a second transverse dimension at the second terminal end of the filter, the second dimension being greater than the first transverse dimension and including vessel engaging structure (27) to retain the filter. Looking at fig. 3A, the first region is being considered the "top" half of the filter and the second region the "bottom half" (examiner is designating 21 to define the "top" of the filter only for illustration purposes). Weldon et al. fails to disclose the first region further including a retrieval region (18) on the first region that includes a hook and the particulars of the hook.

23. However, Bosma discloses that it is old and well known in the art to employ hooks on the end of a filter. Bosma discloses a hook that has a cutout exposing an internal annular surface (Fig. 3 and 4, "22"). As is well known in the art, hooks are employed to ease retrieval of a filtering device by a retrieving device. The hook is meant to ease retrieval by a retrieving device and is therefore dimensioned to receive a portion of a retrieval sheath, such as another hook (col. 5 ll. 8-11). Therefore, it would have been obvious to one of ordinary skill in the art to modify Weldon et al. to have a retrieval region including a hook having a cutout exposing an internal annular surface dimensioned to receive a portion of a retrieval sheath as made obvious by Bosma in order to make retrieval of the device easier.

24. Regarding claim 19, the retrieval region includes a radiused region having first and second curved surfaces extending distally inwardly as seen in Fig. 3 and 4.

25. Regarding claim 20, the hook of Bosma et al. is being considered a single hook with two ears as discussed in more detail above (see paragraph 11).

26. Regarding claim 26, the hooks extend from the mounting section and are positioned at a terminal end of the filter as seen in fig. 2a.

Allowable Subject Matter

27. **Claim 21** would also be allowed if reworded to clarify that *each* hook of the first set of hooks has a transverse dimension greater than a transverse dimension of *each* of the hooks of the second set of hooks. **Claims 22-25** would be allowed if rewritten in independent form with the changes made to claim 21 as recommended by the examiner.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30-5:00, M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KCS
11/17/2006


GLENN K. DAWSON
PRIMARY EXAMINER